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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/728,439

12/05/2003

Scott A. Burton

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03/31/2008

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EXAMINER

RONESI, VICKEY M

ART UNIT

PAPER NUMBER

1796

NOTIFICATION DATE

DELIVERY MODE

03/31/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/728,439	<b>Applicant(s)</b> BURTON ET AL.	
	<b>Examiner</b> VICKY RONESI	<b>Art Unit</b> 1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-45, 48-50, 53-55, 58-60 and 75 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-45, 48-50, 53-55, 58-60 and 75 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> .                                  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :8/20/07, 11/1/07, 11/8/07, 2/19/08, 3/18/08.

### **DETAILED ACTION**

1. All outstanding rejections are withdrawn in light of applicant's amendment filed on 1/8/2008.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior office action.
3. The new grounds of rejection set forth below are necessitated by applicant's amendment filed on 1/8/2008. In particular, the independent claims have been amended to recite that the composition is nonadherent. Thus, the following action is properly made final.

#### ***Claim Rejections - 35 USC § 112***

4. Claims 54 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 42, the use of a tackifier is a nonadherent composition is indefinite because the tackifier would make the composition adherent.

With respect to claim 54, it is indefinite because mineral oil is not a polymer and therefore cannot be the hydrophobic polymer in the composition.

#### ***Claim Rejections - 35 USC § 103***

5. Claims 7-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358).

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Highgate et al discloses a polymer composition for use with surgical operations such as a seal between the skin of a patient and an ostomy appliance (col. 1, lines 20-26) comprising a hydrophobic polymer matrix such as a polyolefin or rubber (col. 3, lines 5-15), 30-70 wt % (col. 8, line 32) a water-swellaable hydrophilic polymer such as vinyl lactam (col. 4, lines 48-65). The composition is optionally made adherent with a tackifier.

Highgate et al fails to disclose (i) the use of bioactive agent such as silver oxide, (ii) water in an amount of 1-20 wt %, and (iii) a water-swellaable hydrophilic polymer having carboxylic acid groups.

With respect to (i), Asmus discloses a composite comprising a hydrocolloid (i.e., water-swellaable hydrophilic polymer) for use with wound care articles and teaches that antimicrobial agents such as silver oxide are incorporated into the to reduce bacteria level and to minimize infection risk (col. 12, lines 16-49). Asmus teaches that the antimicrobial agents are included in the gel components and is therefore contained within the hydrophilic polymer (col. 12, lines 21-36). Furthermore, given that the microbial agents of Asmus are like those presently claimed, the microbial agents intrinsically have a solubility in water of at least 0.1 gram per liter in water.

Given that the composition of Highgate et al is used in wound care and further given that antimicrobial agents such as silver oxide as taught by Asmus are advantageously used to prevent infection in articles for wound care, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a silver oxide in the composition of Highgate et al.

With respect to (ii), Highgate et al does not teach the presence of water, however, Asmus which uses hydrocolloids (i.e., water-swellaable hydrophilic polymer) in its wound-care

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composition teaches that water may be used in the preparation of the hydrocolloids to initiate swelling of the hydrocolloids (col. 9, lines 66-68).

Given that both Highgate et al and Asmus teach the use of water-swellaable hydrophilic polymers and further given that the use of water is desirable to help initiate the swelling of the polymers as taught by Asmus, it would have been obvious to one of ordinary skill in the art to add a sufficient amount of water to the composition, including amounts like presently claimed, in order to initiate swelling. It is the examiner's position that the amount of water is a result effective variable because changing the amount will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

With respect to (iii), Asmus teaches various hydrocolloids (i.e., water-swellaable hydrophilic polymer) and teaches that they includes polyvinyl lactms (like taught by Highgate et al) and polyacrylic acid (col. 6, lines 63-68).

Given that the compositions taught by Highgate et al and Asmus are used in wound care and further given that Highgate et al discloses water-swellaable hydrophilic polymer, it would have been obvious to one of ordinary skill in the art to utilize polyacrylic acid as taught by Asmus as the water-swellaable hydrophilic polymer in the composition of Highgate et al. Case law holds that the mere substitution of an equivalent (something equal in value or meaning, as taught by analogous prior art) is not an act of invention; where equivalency is known to the prior art, the substitution of one equivalent for another is not patentable. See *In re Ruff* 118 USPQ 343 (CCPA 1958).

Note that these claims are product-by-process claims and therefore “even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Therefore, while the presently cited claims recite that a hydroxide source, is added to convert the metal compound into a metal oxide, given that Asmus discloses the use of silver oxide, the final composition of taught by Highgate et al and Asmus and that presently claimed is not different.

6. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358) and further in view of Ahmed et al (US 6,458,877).

The discussion with respect to Highgate et al and Asmus in paragraph 5 above is incorporated here by reference.

Neither Highgate et al nor Asmus discloses the use of a hydrocolloid (i.e., water-swelling hydrophilic polymer) that it is a quaternary ammonium salt of an organic polymer.

Ahmed et al, like Highgate et al and Asmus, discloses superabsorbent polymers (i.e., hydrocolloids) and teaches that quaternary ammonium salts of an organic polymer is a common hydrocolloid (col. 11, line 67).

Given that Highgate et al and Asmus are open to the use of any suitable hydrocolloid material (i.e., water-swelling hydrophilic polymer) and further given that quaternary ammonium

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salts are common hydrocolloids as taught by Ahmed, it would have been obvious to utilize an ammonium salt as taught by Ahmed et al as the water-swelling hydrophilic polymer of Highgate et al.

7. Claims 19-39, 42-45, 48-50, 53, 55, and 58-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358) and further in view of Takemori et al (US 5,075,373).

The discussion with respect to Highgate and Asmus in paragraph 5 above is incorporated here by reference.

While Highgate et al exemplifies a composition comprising a hydrophilic polymer having a particle size of 106-500 microns and fails to disclose smaller sizes of 10 microns and less.

Takemori et al discloses a water-absorbent material like Highgate et al and teaches that the particle size of the water-absorbent hydrophilic resin is fine, particularly less than 40 microns in order for the hydrophilic resin to be readily dispersed in a hydrophobic material and to prevent the hydrophilic resin from being removed from the hydrophobic material (col. 5, lines 10-20).

Given the desirability of using a water-absorbent material having a particle size less than 40 microns as taught by Highgate et al, it would have been obvious to one of ordinary skill in the art at the time of invention to utilize a hydrophilic polymer having a particle size 10 microns and less like presently claimed in order to improve dispersing and retaining properties.

With respect to the utilization of secondary absorbent particles (claims 24, 25, 32, and 33), it is the examiner's position that it is obvious to utilize more than one ingredient that does the same thing. It is well settled that it is prima facie obvious to combine two ingredients, each



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of which is targeted by the prior art to be useful for the same purpose. *In re Lindner* 457 F,2d 506,509, 173 USPQ 356, 359 (CCPA 1972).

8. Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358) and Takemori et al (US 5,075,373) and further in view of Ahmed et al (US 6,458,877).

The discussion with respect to Highgate et al, Asmus, and Takemori et al in paragraph 7 above is incorporated here by reference.

Neither Highgate et al nor Asmus discloses the use of a hydrocolloid (i.e., water-swellaable hydrophilic polymr) that it is a quarternary ammonium salt of an organic polymer.

Ahmed et al, like Highgate et al and Asmus, discloses superabsorbent polymers (i.e., hydrocolloids) and teaches that quarternary ammonium salts of an organic polymer is a common hydrocolloid (col. 11, line 67).

Given that Highgate et al and Asmus are open to the use of any suitable hydrocolloid material (i.e., water-swellaable hydrophilic polymer) and further given that quaternary ammonium salts are common hydrcolloids as taught by Ahmed, it would have been obvious to utilize an ammonium salt as taught by Ahmed et al as the water-swellaable hydrophilic polymer of Highgate et al.

9. Claims 1-4, 6, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358) and further in view of Laurin et al (US 4,603,152).

The discussion with respect to Highgate et al and Asmus in paragraph 5 above is incorporated here by reference.

Asmus fails to disclose the size of the antimicrobial agent (i.e., silver oxide), however, it is the examiner's position that the size is a result effective variable because changing it will clearly affect the type of product obtained. See MPEP § 2144.05 (B). Case law holds that "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Evidence to support the examiner's position is found in Laurin et al which teaches that the size of antimicrobial agent (col. 3, lines 1-8) is critical in controlling the delivery time and tissue irritation considerations, wherein submicron sizes are preferred (col. 4, lines 50-68).

In view of this, it would have been obvious to one of ordinary skill in the art to utilize appropriate sizes of the antibacterial agent, including those within the scope of the present claims, so as to produce desired end results.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358) and Laurin et al (US 4,603,152) and further in view of Ahmed et al (US 6,458,877).

The discussion with respect to Highgate et al, Asmus, and Laurin et al in paragraph 9 above is incorporated here by reference.

Neither Highgate et al nor Asmus discloses the use of a hydrocolloid (i.e., water-swellaable hydrophilic polymr) that it is a quarternary ammonium salt of an organic polymer.

Ahmed et al, like Highgate et al and Asmus, discloses superabsorbent polymers (i.e., hydrocolloids) and teaches that quarternary ammonium salts of an organic polymer is a common hydrocolloid (col. 11, line 67).

Given that Highgate et al and Asmus are open to the use of any suitable hydrocolloid material (i.e., water-swellaable hydrophilic polymer) and further given that quaternary ammonium salts are common hydrocolloids as taught by Ahmed, it would have been obvious to utilize an ammonium salt as taught by Ahmed et al as the water-swellaable hydrophilic polymer of Highgate et al.

11. Claims 13-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Highgate et al (US 4,768,503) in view of Asmus (US 5,270,358) and Laurin et al (US 4,603,152) and further in view of Yan et al (US 2003/0185889).

The discussion with respect to Highgate et al, Asmus, and Laurin et al in paragraph 10 above is incorporated here by reference.

Neither Asmus nor Laurin et al discloses the use of an ammonia source in its composition.

Yan et al teaches that in order to increase the solubility of silver oxide in water, the use of ammonia water is needed (paragraph 0029).

Given that the silver oxide in Asmus is utilized in a water, it would have been obvious to one of ordinary skill in the art to utilize ammonia or any of its derivative salts to increase the solubility of silver oxide as taught by Yan et al.

***Double Patenting***

12. Applicant's statement on page 12 of the response filed on 1/8/2008 regarding the right to argue the patentable distinctness of the below obviousness-type double patenting rejection upon identification of allowable subject matter. If the following double-patenting rejection is the only rejection remaining in this application and if there is a provisional obviousness-type double patenting rejection in the later-filed copending application, per USPTO practice, the examiner will withdraw the rejection.

13. Claims 7-10, 12, and 19-45, 48-50, 58, and 60 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-15, 17-19, 22-25, and 71 of copending Application No. 10/728,577 (published as US 2004/0180093).

US appl. '577 claims a nonadherent wound dressing comprising a composition comprising a bioactive agent like presently claimed, absorbent hydrophilic microparticles like presently claimed, and an organic polymer matrix. Even though US appl. '577 fails to claim a hydrophobic polymer as the matrix polymer, note page 2, lines 16-17, where US appl. '577 discloses the use of a hydrophobic matrix material that is continuous. Case law holds that those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in an application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619,622 (CCPA 1970).

This is a provisional obviousness-type double patenting rejection.

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14. Claims 7-10, 12, and 19-45, 48-50, 58, and 60 are directed to an invention not patentably distinct from claims 2-15, 17-19, 22-25, and 71 of commonly assigned copending Application No. 10/728,577 (published as US 2004/0180093). Specifically, see the discussion set forth in paragraph 9 above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned copending Application No. 10/728,577 (published as US 2004/0180093), discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### ***Response to Arguments***

15. Applicant's arguments filed 1/8/2008 have been fully considered but they are moot in view of the new grounds of rejection set forth above.

***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickey Ronesi whose telephone number is (571) 272-2701. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vasu Jagannathan can be reached on (571) 272-1119. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

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applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

3/18/2008

Vickey Ronesi

/V. R./

Examiner, Art Unit 1796

/VASUDEVAN S. JAGANNATHAN/

Supervisory Patent Examiner, Art Unit 1796